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10/582,894

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Obaidur Rahman

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GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                                      |  |
|------------------------------|--|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/582,894     | <b>Applicant(s)</b><br>RAHMAN ET AL. |  |
|                              | <b>Examiner</b><br>JAGADISHWAR R. SAMALA | <b>Art Unit</b><br>1618              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/14/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group I, claims 1-14 in the reply filed on 08/30/2010 is acknowledged. Applicant's election of species "the synthesis of labeled Kenton" is acknowledged. None elected claims 14-23 are withdrawn from consideration.

- Claims 1-13 are pending in the instant application.

### **Information Disclosure Statement**

The information disclosure statement (IDS) submitted on 06/14/2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Drawings**

The drawing filed on 06/14/2006 has been acknowledged.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1618

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Pelle Lidstrom et al (J. Chem. Soc. Perkin. Trans. 1, 2701-2706, 1997) in view of S.K. Zeisler et al (Appl. Radiat. Isot. Vol. 48(8), 1091-1095, 1997) and Kihlberg et al (WO 02/102711).

Claims are drawn towards a method for labeling synthesis of ketones, comprising various steps.

Pelle Lidstrom discloses synthesis of  $^{11}\text{C}$ -labeled ketones via a palladium-promoted coupling of a halide or triflates with the appropriate tin reagent with insertion of  $[^{11}\text{C}]$  carbon monoxide. The reactions were performed in one pot procedures (abstract). Additional disclosure includes that  $[^{11}\text{C}]$  carbon monoxide at very low concentration was used in the palladium-promoted carbonylative coupling of organic halides and triflates with organotin compounds. The versatile method is rapid, mild, general and conducted in a one pot procedure suitable for automation. The method holds promise for routine production of  $^{11}\text{C}$ -labeled ketones and different carbonyl  $^{13}\text{C}$ -labeled ketones.

Pelle Lidstrom does not specifically teach performing the reaction using boronic acid and  $^{11}\text{C}$ -labeled carbon monoxide using a high pressure reaction chamber.

Zeisler discloses palladium catalyzed cross-coupling reaction of arylboronic compounds with aryl iodides and carbon monoxide as attractive route for the mild

Art Unit: 1618

synthesis of symmetrical and unsymmetrical biaryl ketones. Aryl boronic acids are thermally stable, inert to water and oxygen and can be handled without special precautions. The reaction is substantially controlled by choosing a suitable base and an appropriate solvent to permit the selective coupling even under an atmospheric pressure of carbon monoxide (page 1094). For example, carbonyl labeled benzophenone was prepared by employing [ $^{11}\text{C}$ ] carbon monoxide. Radiochemical purity and specific radioactivity of both [ $^{11}\text{C}$ ] carbon monoxide and the  $^{11}\text{C}$ -labeled ketone are sufficient for nuclear medical studies with PET.

Kohlberg teaches a method and apparatus for production and use of  $^{11}\text{C}$  carbon monoxide in labeling synthesis (title). The  $^{11}\text{C}$  carbon monoxide enriched gas is produced from an initial  $^{11}\text{C}$  carbon dioxide gas mixture (page 1, lines 1-8). The labeling synthesis occurs as follows (page 6):

- Providing a high-pressure reaction chamber having a liquid reagent inlet and a labeling reactant inlet in a bottom surface thereof.
- Providing a liquid reagent volume that is to be labeled.
- Introducing the carbon-isotope monoxide enriched gas-mixture into the reaction chamber via the labeling reactant inlet.
- Introducing, at high pressure, said liquid reagent into the reaction chamber via the liquid reagent inlet.
- Waiting a predetermined time while the labeling synthesis occurs.
- Removing the labeled liquid reagent from the reaction chamber.

The carbon-isotope monoxide enriched gas mixture is produced by (page 5):

- Providing carbon-isotope dioxide with a suitable carrier gas.
- Converting carbon-isotope dioxide to carbon-isotope monoxide by introducing said gas mixture in a reactor device.
- Removing traces of carbon-isotope dioxide by flooding the converted gas-mixture through a carbon dioxide removal device wherein carbon-isotope dioxide is trapped but not carbon-isotope monoxide nor the carrier gas.
- Trapping carbon-isotope monoxide in a carbon monoxide trapping device, wherein carbon-isotope monoxide is trapped but not said carrier gas.
- Releasing said trapped carbon-isotope monoxide from said trapping device, whereby a volume of carbon-isotope monoxide enriched gas-mixture is achieved.

The final pressure of the liquid in the reaction chamber is approximately 80 times higher than the original gas pressure, thus a pseudo one-phase system results (page 11, line 1-10). Additional disclosure includes that advantages are achieved by the apparatus and method are that the resulting labeled compound is highly concentrated, and that the miniaturization of the synthesis system facilitates automation, rapid synthesis and purification, and optimization of specific radioactivity through minimization of isotopic dilution. Most importantly, the method opens a completely new synthesis for producing [ $^{11}\text{C}$ ] carbon monoxide enriched gas mixture from an initial [ $^{11}\text{C}$ ] carbon dioxide gas mixture and using the produced gas mixture in labeling synthesis (page 1 and 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the apparatus and method for production of carbon-isotope enriched gas mixture from carbon-isotope dioxide as taught by Kihlberg and combine with carbonylative cross-coupling using halide or aryl triflates, arylboronic compounds and carbon monoxide to synthesize carbonyl compounds such as ketones as taught by Pelle Lidstrom and Zeisler, and produce the instant invention. One of ordinary skill in the art would have been motivated to make those modifications because Kihlberg teaches a method of producing carbon-isotope monoxide enriched gas-mixture from carbon-isotope dioxide and using the produced gas mixture in labeling synthesis and have advantages such as being rapid, mild, and conducted in a one-pot procedure using an automated apparatus. Kihlberg also teaches that the apparatus and method can be used in palladium-mediated reactions with [ $^{11}\text{C}$ ] carbon monoxide, carbonyl compounds such as aldehydes, ketones, amides, imides and carboxylic acids, has been labeled in high yields. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because Pelle Lidstrom, Zeisler and Kihlberg reference teaches a method and apparatus for production and use of [ $^{11}\text{C}$ ] carbon monoxide for the synthesis of  $^{11}\text{C}$ -labeled ketones.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

Art Unit: 1618

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-8 of copending Application No. 11/344,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and copending application

Art Unit: 1618

involves the method of labeling synthesis comprising similar steps to generate ketones and labeled product. And claims 1-8 of the instant application are well within the scope of claim of the base claim 1 and specially claim 2-7 of the copending application and are properly included in the rejection because they are patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,521,544.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both U.S. Pat. 7,521,544 ('544) and instant application involves the method for labeling synthesis comprising similar steps to generate ketones and labeled product. And claims 1-8 of the instant application are well within the scope of claim of the base claim 1 and specially claim 2-7 of the '544, and are properly included in the rejection because they are patentably distinct from each other.

Claim1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,553,942.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both Pat. 7,553,942 ('942) and instant application involves the method for labeling synthesis comprising similar steps to generate ketones and amides. And claims 1-8 of the instant application are well within the scope of claim of the base

Art Unit: 1618

claim 1 and specially claim 2-7 of '942, and are properly included in the rejection because they are patentably distinct from each other.

Claim 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,667,011.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both Pat. 7,667,011 ('011) and instant application involves the method for labeling synthesis comprising similar steps to generate ketones and carboxylic acids. And claims 1-8 of the instant application are well within the scope of claim of the base claim 1 and specially claim 2-5 of '011, and are properly included in the rejection because they are patentably distinct from each other.

### **Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./  
Examiner, Art Unit 1618

/Jake M. Vu/  
Primary Examiner, Art Unit 1618